TRANSCRIPT OF PROCEEDINGS

IN THE MATTER OF:)
)
STAKEHOLDERS MEETING)
CONTROLLED PHARMING VENTURES)
)

Pages: 1 through 33

Place: Riverdale, Maryland

Date: February 26, 2004

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IN THE UNITED STATES DEPARTMENT OF AGRICULTURE

IN THE MATTER OF:)
)
STAKEHOLDERS MEETING)
CONTROLLED PHARMING VENTURES)
)

Training Room 1
4700 River Road
Riverdale, Maryland

Thursday,
February 26, 2004

The parties met, pursuant to the notice, at 12:49 p.m.

BEFORE: CINDY SMITH
Deputy Administrator

APPEARANCES:

USDA, APHIS and BRS:

REBECCA BECH, Associate Deputy Administrator
SUSAN KOEHLER
JOHN TURNER
NEIL HOFFMAN
MICHAEL WACH

APPEARANCES (CONT.):

For the Controlled Pharming Ventures:

DOUGLAS W. AUSENBAUGH, President

Participants:

LEVIS HANDLEY
CRAIG ROSELAND
MICHAEL BLANCHETTE

P R O C E E D I N G S

(12:49 p.m.)

MS. SMITH: We're going to go ahead and get started. Okay, welcome to our stakeholder discussion series on our upcoming Environmental Impact Statement or EIS and our revised plant biotechnology regulation. We want to thank you for taking time from your busy schedule to participate in this meeting and share your thoughts with us today.

The purpose of these meetings is primarily two-fold. First, to give us an opportunity to share information about our plans to complete an EIS as well as updating our regulations, and then secondly, to gather diverse and informative input which will affect decision making in our upcoming plan revisions.

We have here from BRS most of our management team as well as several other staff members, and when available, other key agency personnel who are involved in supporting BRS in this effort.

I should also mention two key individuals who have now been dedicate to providing full time management of our work to complete both the EIS and our new planned regulations. The first is John Turner, whom I see you have already met. John is a very important member of our leadership team here in

BRS. I'm pleased to say John is providing overall leadership to the effort on a full time basis.

And a second individual, a new face which you may not be familiar with is Michael Wach, a recent BRS hire as an environmental protection specialist within our environmental and ecological analysis unit. In addition to possessing a Ph.D. and an Environmental Law J.D., Michael brings research experience in plant pathology and weed science, as well as legal experience working on cases involving NEPA, the Clean Water Act, the Clean Air Act and other environmental laws.

MR. AUSENBAUGH: Michael, what's your last name?

MR. WACH: W-A-C-H.

MS. SMITH: At this point, I'm going to turn it over to John Turner, who is going to provide you some additional background information and then when John concludes his remarks, then you'll be free to use the time as you'd like.

MR. AUSENBAUGH: Great, thanks.

MR. TURNER: As you may know, we recently had discussions with FDA, EPA and the White House on future regulations. We've concluded that the coordinated framework has worked very well to date

providing a science and risk based approach for biotechnology. But we recognize that under the Plant Protection Act of 2000 there is a unique opportunity for APHIS to revise our regulations and potentially expand our authority, while still leveraging the experience we've gained over the years with the current framework. These revisions might position us well for future advancements of technology.

We concluded the discussions with an overall agreement on how our biotechnology regulatory approach would evolve. Still, it's early in the process and so there is still an opportunity for the public and stakeholder to provide input as we develop the specifics of the regulations. Given this, what we would like to do in these meetings is to give you the opportunity to speak. We want to hear your thoughts and also have an informal give and take on the issues. It's a unique opportunity to have this discussion now, because we're not yet in the formal rulemaking process. So we're free to speak and openly share ideas with stakeholders and the public.

In terms of the transcriber, we're having these discussions professionally transcribed for two reasons. First, we want an accurate record of our discussions to facilitate our ability to capture and

refer to your input in the future. And secondly, in the interest of transparency and fairness to all stakeholders, we will be making public as part of the public record and potentially on our website, documentation on all the stakeholder discussions. So the public and the other stakeholders will have the benefit of the discussions that we will be conducting this week.

I want to emphasize that while we're happy to share information on the direction we're likely to take during the process, what we're sharing is our current thinking. And during the process, public and stakeholder input is going to influence that thinking. In addition to the public and stakeholder input, other officials within USDA, such as the Administrator, the Undersecretary or Office of General Counsel and the Secretary, will also provide insight as well.

So while we value all that, it is important to recognize that our thinking will likely evolve. So while we can have enthusiastic discussions today on any one point, we just need to recognize that it is a part of a process.

MR. AUSENBAUGH: Sure.

MR. TURNER: So on that note, since it's hard to predict exactly what the final regulation

would look like, I'd like to share some overall priority areas of emphasis to set direction and help guide the development and implementation of the regulatory policy.

The first of these is rigorous regulation, which thoroughly and appropriately evaluates safety and is supported by strong compliance and enforcement.

The second is transparency of the regulatory process and decision making to stakeholders and the public and transparency, of course, is crucial to maintaining public confidence.

The next is we want a science-based system. We need to insure the best possible science is used to support regulatory decision making and that helps to assure safety. We recognize the importance of communication, coordination and collaboration with a full range of stakeholders. We also recognize the importance of international leadership to insure that international biotech standards are science based, to also support international regulatory capacity building and we need to consider the international implications of any regulatory decisions that we make.

So with that, I think we're ready to turn the floor over to you.

MR. AUSENBAUGH: Great.

MR. TURNER: Go ahead and state your name one time if the transcriber doesn't have it and the floor is yours.

MR. AUSENBAUGH: Sure, and after our discussions yesterday, Cindy, I felt probably the best method of kind of letting you know who I am and why I'm here is to just prepare a short written statement and I figured I could just read that into the record and then just open it up for an open dialogue.

MS. SMITH: Great.

MR. AUSENBAUGH: I think that will at least put us at a good starting point. My name is Doug Ausenbaugh and I am the founder and president of Controlled Pharming Ventures L.L.C. Our mailing address is 11912 Sand Dollar Circle, Indianapolis, Indiana 46256 and our phone number is (317) 598-0525 and I can be reached via e-mail at doug@ausenbaugh.com.

I responded to BRS' invitation to meet today because Controlled Pharming Ventures' primary business centers on the contained and controlled production of plants and crops that have been genetically engineered to contain pharmaceutical and industrial compounds, which I'll call pharma plants. Our business is affected in a significant manner by the proposed

changes in the APHIS regulations and for that reason I felt it was appropriate to meet with you.

With Purdue University and Indiana University as research partners, we have commenced a proof of concept of a contained production system for pharma plants in a unique underground setting. Our system is designed to offer a safe production alternative for pharma plants while offering a significant value proposition to makers of biologic drugs through reduced costs and drug development time.

As science progresses and the shape of the world's agricultural markets continue to evolve, value-added agricultural research and production, including that of genetically engineered crops in the United States, has become increasing important. Pharma plants in particular offer the promise of creating life-saving biological drugs for humans and animals safer, faster and cheaper. However, confinement concerns of pharma plants produced in a field environment have hampered research activity and investment in the area. This incomplete research has caused the benefits of plant-made pharmaceuticals to remain undefined, possibly reducing future research investment even more. This potential "catch-22" threatens a valuable solution that could eliminate

capacity concerns for biologic drugs for both humans and animals and reduce the cost of health care.

Controlled Pharming Ventures supports the notion that the integrity of the food production system and the safety of the environment are of paramount importance in establishing the regulatory framework for genetically engineered organisms. The efforts of the USDA and other agencies help make our agricultural production system second to none by establishing practical, science-based regulations.

We support APHIS' consideration of a new mechanism involving APHIS, the States, and the producers of pharma plants for confined development and production. Until biologic confinement is assured, physical confinement and containment is necessary and adventitious presence of pharma plants should be prevented. The benefits of confinement and containment include:

The isolation of the pharma plant from the ecosystem addressing environmental impact concerns.

The ability to regulate a contained production system more efficiently.

Regulatory compliance is easier to audit.

An infrastructure totally separate from the food production system;

And locations can be hidden from view and secured against risk including natural disaster, disease and terrorist attacks.

In summary, plant-made pharmaceuticals offer the potential to ease capacity concerns of biologic drug production while offering a potentially safer and less expensive alternative. Physical containment and confinement of pharma plants offers a practical, scalable and cost effective alternative while maintaining the safety of our agricultural production system.

The mechanism APHIS is considering as discussed previously will address concerns of pharma plant production and stimulate research in this very important area.

Thank you for your time and with that, I guess I'll just open it up for questions. Hopefully, I've generated a few.

MS. SMITH: Okay, and you can certainly ask us any questions for clarification you have about our Federal Register notice, as well.

MR. AUSENBAUGH: Sure, I do have one question and it primarily deals with number six on page 3272 where you talk about the new mechanism. I assume you're looking at a separate permitting process

that would involve the states as well as some predefined regulations of APHIS and like you said, the producers to get that done?

MS. SMITH: Yes, we're open to what the mechanism will look like, but generally what you're talking about is accurate. Some separate or some unique regulatory mechanism that we would use that could provide more transparency and it could be more efficient as we look at essentially the situation where field tests would need to be conducted year after year for commercialization purposes. So that generally is what we're talking about. And we're open for suggestions about what that should be.

MR. AUSENBAUGH: Sure, okay.

MS. SMITH: I have a question for you.

MR. AUSENBAUGH: Sure.

MS. SMITH: You referred t the approach that you're taking is one that's scalable. Can you give us a sense if you're working underground what kind of scale we can talk about?

MR. AUSENBAUGH: Our prototype facility and I've actually got a couple pictures of it I can share with you is, we're putting our prototype facility in a three million square foot, I'll put it a depleted limestone mine that is now a working warehouse in

southern Indiana. We've done a lot of preliminary estimates with folks that have done limestone mining in the past and we estimate that there's tens of thousands of acres of this type of space available in the United States.

Not only that, but because limestone mining produces revenues, new space can be created as needed. There are a number of unique features that make this a potentially attractive alternative. Number one of which is just the natural physical security of the space. There's one way out, there's one way in, one way out. It is a space that has a very stable climatic environment, from a temperature standpoint, in that the temperature is about 51, between 51 and 53 degrees. It's naturally totally dark, so whenever our official light is used, the heat from the lights is used to heat the crop.

One of the road blocks in contained production above ground is a changing temperature occasionally and you also have heat build up. With all the limestone that we have, we have a natural heat sink and we can really control the temperature as much or as little as we want.

There is also a number of environmental conditions which are not necessarily for corn, but for

other types of plants, are beneficial for plant growth in terms of yield enhancement, whether it be enhanced natural CO_2 levels or the ability to change the environment. But there is a lot of this type of space available, and frankly, we are designing our system so that if it is necessary to be done in a warehouse, for instance, that it could be done.

MR. HOFFMAN: What sort of crops are you thinking of?

MR. AUSENBAUGH: We are going to start with corn and that was based on a lot of market research that we've done. Corn for a number of reasons makes a lot of sense to us. Number one, if we can design a system that can grow corn effectively, we can probably grow just about anything. Corn has kind of shown to be one of the most difficult things to grow in a contained and controlled environment using totally artificial light.

From an intellectual property perspective, there is a lot of work being done on corn and a lot of ability for more work to be done on corn. And then also just the inherent work ability that corn has shown in the past with regards to genetic engineering.

We're also probably depending on funding. We'll look into doing some alfalfa and tomatoes

upfront, as well. We also have considered a number of very leafy vegetables. We are working with a gentleman at Purdue University by the name of Dr. Cary Mitchell, who is a controlled environment specialist at Purdue. He has done a lot of work with NASA with regards to the optimization of inputs for a potential trip to Mars, for instance. How do you grow crops quickly and efficiently? And we hope to use some of that technology to enhance a value proposition for producers of pharma plants.

MR. WACH: Some of the biotechnology events, you'll be developing other, some of your space would be contracted out for other people to use?

MR. AUSENBAUGH: I think from a business plan standpoint, we had originally envisioned being a contract research facility, in essence, where if folks needed research performed on these pharma plants that they wanted to turn around, that was what we had originally envisioned.

In further discussions with potential users of this facility, we see the potential if we're able, to show how we can optimize growth and accelerate growth in these types of crops. We see the potential as a true production alternative from a contract manufacturing standpoint.

As the use of biologic drugs increases, a trend that follows right with that is the increasing outsourcing of manufacturing services and that's, from a business standpoint, I think that's the niche that we've targeted at this point.

MR. WACH: So you may actually do the extraction underground as well?

MR. AUSENBAUGH: That's down the road. For the purposes of this discussion, our goal is to work with the folks that are trying to grow pharma plants and help them grow them most effectively. If somebody came to me today and said that they wanted to do that, I would tell them that we would help them grow the plant and then they would be responsible for the extraction. At some point, it's probably feasible or makes sense to do the extraction and purification at a close location to where we have these facilities and we do have ample room for that, for instance, at our prototype facility.

MR. ROSELAND: If you had multiple crops of the same type, don't you enhance your possibilities of gene flow to those crops in an underground situation?

MR. AUSENBAUGH: Just because there's no other way out, is that --

MR. ROSELAND: Just because everything is

confined. When pollen is produced, it's going to be everywhere within your facility.

MR. AUSENBAUGH: First of all and you'll have to forgive me, because I could sit here and talk about what the facility looks like for hours and show you pictures. Until you actually see the facility, it doesn't do it justice.

That is less of a concern to me than it originally was. There is a lot of natural containment and areas of our facility can be segregated very well. Part of what our aim would be would be the ability to meet, for instance, NIH guidelines with regards to biosafety levels as necessary.

Again, we've got a very good kind of starting point for that type of containment. My sense would be that if we were to ever get into commercial production, the need for numerous physically separate facilities like this would be necessary.

MR. HOFFMAN: So do you have a prototype that's already been built?

MR. AUSENBAUGH: We've got a prototype on paper. We hope to have a prototype up and running by the end of the summer with Purdue University. Controlled Pharming Adventures was started last summer, around the same time that we met. And between

then and now, again, we've joined up with Purdue University from a controlled environment perspective, and Indiana University from a warm place, safety perspective, to move forward on our technology. And we just recently were awarded, subject to state budget committee approval, a $2 million grant from the Indiana 21st Century Research and Technology Fund to build the prototype and to do the feasibility study.

We've also applied for an NIH grant for the Small Business Biodefense Program, where our aim would be to help accelerate the production of drugs aimed toward the pathogens on the priority list.

MR. HOFFMAN: So my picture of a mine is a very dark, dingy, dirty place. I'm just wondering to what extent do you have ventilation?

MR. AUSENBAUGH: As I said, this is a working mine. It's over three million square feet. A small portion of it right now is being used by a large tire company. They have over one million tires in one part of the mine over here that they use for, you know, for inventory.

We have the ability to, that's a finished outportion of what we're doing. Ironically, I don't have that picture with me. I can get you additional pictures if you'd like and I'd be more than happy to.

But it's pretty neat.

You drive into the side of a cliff, in essence, and you can literally drive a semi-truck in there and turn it around. We figure that we've got, right now, if everything were, we could build out over 60 acres of production space in this one particular facility.

There are numerous other locations. I've spent most of my time in locations in Indiana. There is a north 100 acre potential facility on the south side of Indianapolis and there are others around the country. As I said, there are actually other working warehouses, as well, of this type. We just happened to be blessed in Indiana to have one like this that is just a terrific facility from an infrastructure perspective. We've got plenty of water and power.

MR. TURNER: Back to Neil's question. When you started, I imagine it was rocky walls or something. Did you build it out to seal it, the sides?

MR. AUSENBAUGH: The way limestone is mined and I'm trying to remember the exact -- it's called the pillar and table method, I think. I'm not sure of the exact way it's called. But essentially when you go in there to try and describe what it is, it's like

if you're in a convention center and there are these huge rooms that are just long. And every 20 feet or so there is a 20 foot square pillar, but then there's this real long, it's almost, you know, if you're walking in there with an underground pharming hat on, you see these potential very long rows of crops with all these staging areas on each side of them that you could grow. So it's, this facility in particular is very large. We think that it will meet our needs for the next couple of years. But, you know, part of what from a business standpoint, again, what we're selling, is a scalable solution and we hope to be able to emulate this in other areas.

MS. KOEHLER: How would you envision the cost of contracting with you to grow say, pharmaceutical producing corn, compared to someone being able to grow it in a field?

MR. AUSENBAUGH: Right. From a field production standpoint, we cannot compete on just an absolute dollar for dollar cost basis. Until we actually grow the crops in a facility, we will not have, from an overall infrastructure build out, we estimate that our costs will be very similar to that of an above ground greenhouse.

Our base space is substantially less. Our

lighting cost is actually going to be higher. We do think that our overall operating costs underground will be lower than they would be above ground. We will have a higher lighting cost, but the power cost will be less because we don't have to artificially cool it.

We hope to add value to the producers of these types of crops by, number one, enhancing yields, speeding up time of production. WE think that we've got the potential to maybe put out four generations of corn per year using the same space. If we're able to do that and enhance yield, certainly, even though the absolute dollar costs on a field test basis might not be the same, I can probably go to a -- probably look at a field test and put into play a lot of intangible costs that we wouldn't have with our solution.

MR. WACH: If you're going to have four crop turnovers a year, what are you going to do with -- I assume this isn't going to be hydroponic? They're going to be in soil?

MR. AUSENBAUGH: We're going to start with using pots of some sort of growth medium. At that point, I don't know. I could certainly get back to you with --

MR. WACH: So you're going to have a lot of

soil, I assume you're going to reuse that, so you don't have to get rid of it?

MR. AUSENBAUGH: We would dispose of it. This is all part of the framework that we're still developing. It can be autoclaved and disposed of, but yes, we have, we realize that's all part of the questions that we still need to answer.

Depending on what we were growing, and again, we're hoping to build a robust system, that if somebody comes to us and says, we'd like to use a hydroponic system, we could be able to accommodate them. At one point we looked at almost a traditional farming solution, where we could literally ship in the dirt and put it on the floor. What we might put under that, I don't know. And you know, that's something that could potentially happen at some point, but at this point, we're going to start our proofing concept using pots.

MR. WACH: Are you part of an aquifer based system?

MR. AUSENBAUGH: We would draw on city water.

MR. WACH: But are you, because aren't there some aquifers in the area? If you were to have, if some of the pharmaceuticals, for instance, are to be

used by roots, could you have --

MR. AUSENBAUGH: Thus far, we have been able to be satisfied that we can contain anything that we would have. It's a very dry mine, a very secure mine. Keeping in mind that from the type of physical containment that we're talking about, we're fully cognizant that we are going to control our runoff and go to lengths, you know, again, following potential biosafety levels that, you know, we will definitely contain that type of waste runoff.

MR. WACH: Do you perceive it being the responsibility of the owner, I guess it would be the owner of the plants, to deal with testing, testing of residues in the soil, testing of residues in the climature? Or are you going to provide that --

MR. AUSENBAUGH: I think that would be a joint responsibility between us and our partner. Our first tests, our first feasibility tests are going to be on plants that are exempt from NIH guidelines. What that does is that gives us the time to make sure that our system is -- I can't think of the word -- make sure we've got a good, tight system, a system with a lot of integrity.

MR. HOFFMAN: So you said you were going to contain the water, but you would need an awful lot of

water. I just wondered if you thought about water treatment?

MR. AUSENBAUGH: Yes, yes,and when I talk about containment, we're going to contain the water until its treated, until it's deemed to be safe to be released. And, you know, we've looked at a number of different ways to utilize the water with regards to if we need to warm the roots, potentially running the water over, you know, in some kind of barrier to heat it by the growth lights and then run down through the roots to keep them warm.

Again, it's going to be really contentioned upon what kind of crop we use. So, but you know, our business is focused on offering that type of contained solution and taking all of those variables into account.

MR. HOFFMAN: Now you said your access to this is on a road level, you just drive a truck in there?

MR. AUSENBAUGH: Yes, it's essentially --

MR. HOFFMAN: It's a hill or a cliff?

MR. AUSENBAUGH: What you're doing is you're driving into the side of a cliff. And it's almost like an underground industrial park. There is essentially a shared main entrance, but then the

numerous roads fork off. So we would have a, you know, our own contained controlled ingress and egress from our particular space that we need demise appropriately.

MR. ROSELAND: Are you going to need special plants that are adapted to artificial environments?

MR. AUSENBAUGH: That will be part of our initial research. We're actually going to look at four different strains. We have a commercial partner who is going to supply us with different types of seeds that do different things at different temperatures and are proof positive will tell us which one is most effective and how it will be used the best.

MR. ROSELAND: Are those also genetically transformed plants or not?

MR. AUSENBAUGH: We're probably going to start with BT corn, just to, from the very initial, to help us kind of optimize our growth from corn. And then after we've established that proven concept, our next step will be to talk to potential users of pharma plants, true pharma plants, once we've got our system set up.

MR. WACH: I want to see it. I want a tour.

MS. KOEHLER: Have you visited any of the

other mines that are already engaged in this kind of business?

MR. AUSENBAUGH: I only know of one other company that's doing that and that's a company called Prairie Plant in Canada. I made an attempt a long time ago and I'm sure it was perceived as a direct competitor, so I frankly haven't had a lot of conversations. Again, from a business standpoint, the underground facility is what I call the sizzle in the steak, where we're trying to add value to potential users of our facility is number one, just the overall containment and, number two, and what is probably more important in a different form, but the ability to really speed this type of production up and enhance production by optimizing the inputs.

I mean, we are fully aware that we are going to be more expensive than traditional field production. But if we're able to potentially generate four generations of corn a year and we're able to show that we can shave drug development time off, that's a very large and valued proposition to drug makers.

MR. WACH: Do you filter the air?

MR. AUSENBAUGH: Oh, yes. We will, yes. We've got air tests scheduled on a regular basis.

MR. HOFFMAN: And plus plants are sensitive

to certain volatiles. Like you mentioned you've got all these tires that are stored there.

MR. AUSENBAUGH: Right.

MR. HOFFMAN: Those tires are going to give off gases that are going to affect the growth of the plants.

MR. AUSENBAUGH: Exactly, and again, I wish I could take you there right now. We will have a totally separate and contained facility from that. I mean, actually, that's the first thing that ran through my mind and we were actually looking at different ways. I don't know how well you can see it in this picture, but they've actually demised a lot of it using concrete block where there's not natural limestone.

One of the things we looked at was potentially using some sort of biodegradable shrink wrap for containment purposes. We're still trying to figure out whether or not what we're looking at off gases and whether that will affect the growth of the plants. We don't know yet.

MR. HOFFMAN: I couldn't tell what the walls were there. Is that some --

MR. AUSENBAUGH: That's limestone. That's the actual limestone that they've white washed.

MR. HOFFMAN: And will water have an effect? There's going to be a lot of humidity there now. What effect will that have on limestone? The stalactites and --

(Laughter.)

MR. AUSENBAUGH: Right, a couple of things to keep in mind. First of all, this is not a cave. This is a man made mine. A lot of the mines that I've been in in actually finding this one do have water problems. The humidity in this particular mine does change. Part of our system will be to monitor and control that humidity. Typically in the summertime is when you have humidity issues. From a plant growth perspective, we like humidity. The only potential problem that we've uncovered thus far with the actual physical infrastructure is a possibility that if it gets too hot, you will start getting some sort of cracks. That will not be the issue with our facility, because we will maintain a higher degree of humidity. I mean, it will be humid in our space, regardless of what the humidity is on the other side of the wall.

MR. HOFFMAN: Are you going to put cooling in there as well?

MR. AUSENBAUGH: We don't think we're going to need cooling. It's, as an aside, one night I took

Dr. Mitchell down from Purdue all the way down, it's about a two and a half hour drive from Indianapolis, and all the way down, he was talking about and worried about heat build up and how are we going to get rid of the heat? Once I got him out there, he was more worried about keeping the heat in. I mean, it's just a very massive type of space.

MR. HOFFMAN: So you could have a pretty good fluctuations in temperature just by turning the lights on and off?

MR. AUSENBAUGH: We will have, again, we're starting at about 51 degrees, but the good news is we're starting at 51 degrees every single days.

MR. HOFFMAN: Well, I think you want fluctuations in temperature.

MR. AUSENBAUGH: Yes, right. And, you know, we will have the ability if we need to contain the heat, we can. I mean, if we need to build a big, underground cooler, you know, styrofoam walls all the way around to contain it, naturally we're going to have a lot of light and this light, the type of light that grows plants best is very inefficient light. We're fortunate enough to be in a starring position where we can use basically all of that heat for our facility. And that's also why we feel our utilities

costs are going to be competitive or cheaper than compared to that with above ground space.

MR. BLANCHETTE: Obviously, you're going to have to go in and out. How are you going to maintain that containment?

MR. AUSENBAUGH: That's part of the overall plan. WE're working closely with Purdue, as well as a contained environment engineering firm to come up with the process that that's done properly. We'll be using totally dedicated equipment, naturally and, you know, I know that that's part of the regulations with regards to dedicated equipment. And is it dedicated for one particular crop? We're certainly willing to work with whatever is the safest way, safest from a scientific basis.

MR. WACH: What about things like rats, mice?

MR. AUSENBAUGH: Believe it or not, unless you bring food in here, which we will be bringing food in here, it is shown to be a totally pest free facility. As in any field environment, we are fully aware of the possibility of that type of infestation and will address it as it happens. We do think that our risk of plant disease, we do think our risk, that the risks of, you know, infestation and the like, will

be severely -- not severely, substantially less than above ground.

MS. KOEHLER: What about waste, plant waste disposal? Are we building some kind of an incineration facility adjacent to this?

MR. AUSENBAUGH: If things go well and we have a lot of waste like that, yes. If not, it will be transported in a manner that conforms with all of the regulations and disposed of properly.

MS. SMITH: Okay, why don't we see -- okay, I was going to suggest, it sounds like we've got a lot of interest here in the technology, probably not a lot of specific questions about our notice. If there's any final questions or clarifications we can give you about our notice itself, let's move to those. And if not, what we could do is break the group and take our transcriber off the clock and have informal conversation after.

MR. AUSENBAUGH: Okay. I think just in closing that I'd like to say that from a personal perspective as well as Controlled Pharming Venture's perspective, I support what you're doing and I think it makes a lot of sense. And I also think that as I said in my opening comments, that a contained production solution for these types of plants, these

types of very high value plants, is not only feasible, but it's very cost effective and it is a way to get potentially life saving drugs to market safer, faster and cheaper. And with that, I thank you.

MS. SMITH: Okay, any final questions before we break? Okay, thank you for coming in. This has been very interesting discussion. We appreciate your time.

MR. AUSENBAUGH: Thank you.

MS. SMITH: Thank you.

(Whereupon, at 1:27 p.m., the meeting was adjourned.)

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REPORTER'S CERTIFICATE

DOCKET NO.: N/A

CASE TITLE: Stakeholders Meeting

HEARING DATE: February 26, 2004

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: February 26, 2004

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